K063766

510(k) SUMMARY

APR 23 2007

Safety and Effectiveness

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

Transferrin TIA/ Transferrin Calibrator Set /
Transferrin Control-L, Control M, Control-H

Submitter	
Name,	Good Biotech Corp.
Address,	38 34th Rd. Taichung Industrial Park Taichung City 407 Taiwan
Telephone number,	+886-4-23596873
Contact person,	Victor Chiou
Preparation date	12/15/2006
Device	
Trade name,	Transferrin TIA Transferrin Calibrator Set Transferrin Control-L, Control M, Control-H
Common name,	Serum Transferrin immunological diagnostic assay Transferrin calibrator Transferrin control
Classification name	Transferrin immunological test system (21 CFR § 866.5880) Calibrator (21 CFR § 862.1150) Quality control material (assayed and unassayed) (21 CFR § 862.1660)
Predicate Device	
Trade name,	Roche Tina-quant Transferrin ver.2
510(k) number	K012393

Description

Good Biotech Corp. Transferrin TIA is a ready to use reagent for the quantitative determination of transferrin in human serum by turbidimetric immunoassay (TIA). When transferrin of the serum sample encounters with duck anti-transferrin antibody, the agglutination based on the antigen-antibody reaction increases the turbidity of the sample. The value of the absorbance change at 505 nm is proportional to the transferrin concentration of the sample and is recorded by a general chemistry autoanalyzer. Then, the actual transferrin concentration of the serum sample is determined by interpolation of the calibration curve obtained by standard samples with known transferrin concentrations.

Intended Use

Reagent:
Good Biotech Corp. Transferrin test system is intended to be used for the quantitative determination of transferrin in human serum by turbidimetric immunoassay (TIA). Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

Calibrator:
Good Biotech Corp. Transferrin Calibrator Set is intended to be used with Transferrin TIA for the quantitative determination of transferrin in serum samples.

Control:
Good Biotech Corp. Transferrin Controls are intended to be used as the assayed quality control material for transferrin analysis.

For In Vitro Diagnostic Use.

Substantial Equivalence

Comparative performance studies conducted on 82 serum samples yielded high correlation coefficients upon comparison of the GBC Transferrin TIA system and the predicate devices,

Roche Tina-quant Transferrin ver.2. The results are summarized below:

Comparative Method	Slope	Intercept (mg/dL)	Correlation Coefficient	n
Roche Tina-quant Transferrin ver.2	0.927	19.784	0.992	82

Conclusion

Good Biotech Corp. Transferrin TIA system, calibrator set and controls are substantially equivalent to the predicate devices based on their intended purposes, design and the comparison performance results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Good Biotech Corporation
c/o Mr. Victor Chiou
President
38 34th Road
Taichung Industrial Park
Taichung 407 Taiwan

APR 23 2007

Re: k063766
Trade/Device Name: Good Biotech Corp. Transferrin TIA
Good Biotech Corp. Transferrin Calibrator Set
Good Biotech Corp. Transferrin Control-L. Control-M, Control-H
Regulation Number: 21 CFR 866.5880
Regulation Name: Transferrin Immunological Test System
Regulatory Class: Class II
Product Code: DDG, JIT, JJX
Dated: March 26, 2007
Received: March 26, 2007

Dear Mr. Chiou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

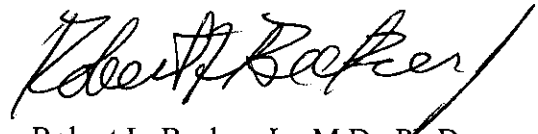
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K063766

Device Name: Transferrin TIA
Transferrin Calibrator Set
Transferrin Control-L, Control-M, Control-H

Indications For Use:

Good Biotech Corp. Transferrin test system is intended to be used for the quantitative determination of transferrin in human serum by turbidimetric immunoassay (TIA). Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia

Good Biotech Corp. Transferrin Calibrator Set is intended to be used with Transferrin TIA for the quantitative determination of transferrin in serum samples.

Good Biotech Corp. Transferrin Controls are intended to be used as the assayed quality control material for transferrin analysis.

For In Vitro Diagnostic Use.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria M Chan

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(510(k)) K063766